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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,202	11/21/2003	Zeren Gao	00-46C1	5147

10117 7590 09/07/2006

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EXAMINER	
JIANG, DONG	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 09/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/719,202	GAO, ZEREN	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) *15-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-28* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/21/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED OFFICE ACTION

Applicant's election of Group I invention, claims 1-14, filed on 18 July 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Currently, claims 1-28 are pending, and claims 1-14 are under consideration. Accordingly, claims 15 and 28 are withdrawn from further consideration as being drawn to a non-elected invention.

Formal Matters:

Information Disclosure Statement

Applicant's IDS submitted on 11/21/2003 is acknowledged and has been considered. A signed copy is attached hereto.

Priority acknowledgement

This application claims benefit of U.S. application 09/899,471 filed on 7/5/01, and U.S. provisional application 60/366,426 filed on 7/6/00, which is acknowledged.

Specification

Title

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the elected claims are directed.

Rejections under 35 U.S.C. §101 and §112:

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 10 is rejected under 35 USC §101 because the claimed invention is directed to non-statutory subject matter. The term "a *recombinant* host cell" reads on isolated host cells, as well as genetically modified host cells in the context of a multicellular, transgenic organism and host cells intended for gene therapy. The specification teaches that the nucleic acid of SEQ ID NO:1 can be used for gene therapy or generating transgenic animals (page 79, lines 15-29, and the paragraph bridging pages 79 and 80), indicating said cell becoming integrated into the human being and therefore being an inseparable part of the human itself. The scope of the claim, therefore, encompasses a human being, which is non-statutory subject matter. As such, the recitation of the limitation "isolated" or "non-human" (instead "recombinant") would be remedial. See 1077 O.G. 24, April 21, 1987.

Claims 1-14 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Claims 1-14 are directed to an isolated nucleic acid encoding a polypeptide having SEQ ID NO:2, a vector and a host cell thereof, a method of recombinant expression of such, and a composition comprising said nucleic acid. The encoded polypeptide is a putative cytokine receptor, and designated Zcytor14.

The specification discloses a nucleic acid of SEQ ID NO:1 encoding a murine cytokine receptor of SEQ ID NO:2. Based on the sequence study, Zcytor14 polypeptides share sequence homology to the known human IL-17 receptor. Accordingly, the specification asserts, at page 70 (the last paragraph), that polypeptide having Zcytor14 activity can be used to treat inflammation, and conditions such as rheumatoid arthristis, that are associated with inflammation (as IL-17 activates the production of inflammatory mediators and contributes to the proinflammatory patterns that is characteristic of RA). Additionally, the specification asserts the use of Zcytor14 nucleotide sequences as a probe for detecting gene expression (page 63, the last paragraph), to provide Zcytor14 for treatment; a therapeutic expression vector comprising a molecule such as the anti-sense, or a ribozyme to inhibit Zcytor14 gene expression (page 75, lines 25-28), and the production of transgenic mice (page 79, the last paragraph).

The asserted utilities are not considered to be specific and substantial because the specification fails to provide specific support therefor, such as information about a particular

functional activity or biological significance *directly associated with* Zcytor14 polypeptide, or any known ligand for the putative cytokine receptor of the instant invention.

Generally, the art acknowledges that function cannot be predicted based solely on structural similarity to a known protein. For example, IL-18 receptor (IL-18R) was thought to be another IL-1 receptor (IL-1R) base on the sequence homology, and therefore, designated IL-1 receptor-related protein (IL-1Rrp) when it was first discovered, and its ligand was unknown (Parnet et al., J. Biol. Chem., 1996, 271(8): 3967-70). IL-1Rrp is now known as IL-18R, has distinct ligand, and possesses distinct function from IL-1R even though it is a member of IL-1R family. Additionally, Skolnick et al. (Trends in Biotechnology, 2000) teaches that because proteins can have similar structures but different functions, determining the structure of a protein may not necessarily reveal its function (see entire article, especially Box 2). Therefore, an established utility for IL-17 and IL-17R cannot be automatically applied to "Zcytor14" polypeptide without functional analysis, especially given the fact that the ligand of Zcytor14 and the expression pattern are not known, and IL-17 does not seem to bind Zcytor14. It is not even clear whether Zcytor14 is expressed in, for example, joint related tissues. While it might be possible that the Zcytor14 protein is a member of IL-17R family, that by itself does not suggest any specific or substantial utility for the reasons above.

The disclosed uses for the nucleic acid in producing the polypeptide, gene therapy, and as a pharmaceutical composition are not specific and substantial in the absence of knowledge of the ligand which said receptor binds, any biological property of the receptor protein, or any disclosed gene mutation, or any disease or condition which could be so diagnosed, or treated. Therefore, there is no immediately evident patentable use for the claimed Zcytor14 nucleic acids. Upon further research, a specific, and substantial utility might be found for the claimed isolated nucleic acids or for the polypeptide encoded thereby. This further characterization, however, is part of the act of invention, and until it has been undertaken, the claimed invention is incomplete.

Until a specific and substantial utility can be attributed to the IL-17RL nucleic acid or the polypeptide encoded thereby, or a credible disease association established, uses such as a probe for detecting gene expression, and generating transgenic animals, are not considered by the Patent Office to be a specific or substantial utility, as such uses could be asserted for *any* cDNA.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-14 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Rejections under 35 U.S.C. 112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11, 12 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 is indefinite for failing to adequately point out what applicants see as the invention, as the host cell may produce polypeptides other than the polypeptide encoded by "the DNA segment", it is unclear whether "a polypeptide" (line 1) is the same as "the polypeptide encoded by the DNA segment" (lines 3-4), as there is no direct link between the two. The claim should be amended to indicate the identity of "a polypeptide" being *produced*.

Claim 14 is indefinite for the recitation "signal sequence is operably linked to first portion *and* second portion" as it is unclear whether the signal sequence linked to first portion and second portion, respectively, i.e., two peptides are being produced; or the signal sequence linked to first portion, and the first portion is linked to the second portion, i.e., one fusion protein is being produced.

Claim 12 is included in this rejection because it is dependent from the specifically mentioned claims without resolving the indefiniteness issue belonging thereto.

Prior Art:

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Gorman (US 2003/0092881) discloses a nucleic acid, SEQ ID NO:7, which nucleotide sequence comprises the nucleotides 1-2022 of the present 11 with 96.4% sequence identity, and encodes a polypeptide (SEQ ID NO:8) with 96.1% sequence identity to the present SEQ ID NO:2 (see computer printout of the search results).

Conclusion:

No claim is allowed.

Advisory Information:

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Dong Jiang

Dong Jiang, Ph.D.
Patent Examiner
AU1646
8/28/06